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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/633,793	08/07/2000	Thor Halseth	1032-P01510US1	3022

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DANN DORFMAN HERRELL & SKILLMAN  
SUITE 720  
1601 MARKET STREET  
PHILADELPHIA, PA 19103-2307

EXAMINER

GHAFOORIAN, ROZ

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/633,793

Applicant(s)

HALSETH ET AL.

Examiner

Roz Ghafoorian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 and 14-58 is/are pending in the application.
- 4a) Of the above claim(s) 16-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 August 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Newly submitted claims 16-58 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 16-58 read on other embodiments not selected by the applicant in the original claims 1-7.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16-58 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-4, 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S Patent 4838869 to Allard or US Patent No.5984898 to Garvin.

Allard or Garvin apparatus provides a sampling device with a housing and a retractable needle in the plunger, with rearward bias. Both Allard and Garvin teach syringe is capable of collecting fluid form the patient and seal it in the housing as well as expelling the fluid form the housing with a plunger.

3. Claims 1-4, 14-15 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S Patent No.6179812 to Botich et al or US Patent NO.6123688 to Botich et al, or US Patent No.609077 to Shaw or US Patent No.6015438 to Shaw or US Patent No.6036674 to Caizza et al

Gibbs discloses a non-reusable medical needle apparatus. Gibbs's apparatus provides a sampling device with a housing and a retractable needle. The fluid, which has been, collected form the patient may be sealed in the housing and then expelled form the housing after the needle has been retracted. (Figures 38-42)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 5-6 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No.6179812 to Botich et al or US Patent NO.6123688 to Botich et al, or US Patent No.609077 to Shaw or US Patent No.6015438 to Shaw or US Patent No.6036674 to Caizza et al or U.S. Patent 4838869 to Allard or US Patent No.5984898 to Garvin.

As mentioned above, both Gibbs and Alexander's apparatus provide a sampling device with a housing and a retractable needle. Furthermore, the fluid, which has been collected from the patient may be sealed in the housing and then expelled from the housing after the needle has been retracted. Neither Gibbs nor Alexander discloses the analysis of the pH level of the collected fluid. However, it is common practice in medicine to analyze the collected fluid, for the most part with a few exceptions, the fluid is collected for the sole purpose of some type of analysis. The type of analysis done to the collected fluid (i.e. pH level) depends on the singe, the symptom, past medical history, current potential diagnosis, and family history of the patient. In case of analysis of pH level in bodily fluid, it is mostly indicated whenever a clinically important acid-base disturbance occurs, for example when hypoxemia or hypercapnia are suspected. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the fluid collected from the patient for some type of analysis (i.e. pH level) to help with the diagnostic or treatment process.

#### ***Response to Arguments***

5. Applicant's arguments filed 12-4-2002 have been fully considered but they are not persuasive.

Applicant's arguments with respect to claims 1-7 and 14-15 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. Any inquiry of a general

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nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

RG  
February 6, 2003

A handwritten signature in black ink, appearing to be 'RGL'.A handwritten signature in black ink that reads 'Michael J. Hayes'.

**MICHAEL J. HAYES**  
**PRIMARY EXAMINER**